IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
GREAT FALLS DIVISION

ENVIRONMENTAL DEFENSE FUND; MONTANA ENVIRONMENTAL INFORMATION CENTER; and CITIZENS FOR CLEAN ENERGY, *Plaintiffs*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY; and ANDREW R. WHEELER, in his official capacity as Administrator of the U.S. Environmental Protection Agency, *Defendants*.	Case No.: 4:21-cv-00003-BMM-JTJ The Honorable Brian Morris, Chief Judge

DECLARATION OF DR. JEREMY SARNAT

I, Dr. Jeremy Sarnat declare as follows:

1. I am an Associate Professor at the Emory University Rollins School of Public Health. My primary areas of interest are air pollution, epidemiology, and exposure assessment. My research focuses on characterizing human exposure to urban air pollution.

2. I received my Doctor of Science degree in Environmental Health and a master's degree in Public Health from Harvard University in 2001 and 1998,

respectively. I received my bachelor's degree in Anthropology from the University of Michigan in 1990.

3. I was a panelist on the Environmental Protection Agency's (EPA) Science Advisory Board for Particulate Matter, which is part of Clean Air Scientific Advisory Committee which provides independent advice to the EPA Administrator on the technical bases for EPA's National Ambient Air Quality Standards, before EPA disbanded the Science Advisory Board for Particulate Matter in 2018.

4. I am a member of Environmental Defense Fund because I believe in its mission to advocate for science-informed policy and decisionmaking.

5. My deep interest in environmental exposure science is motivated by the many epidemiologic and toxicologic findings linking air pollution to a range of adverse health endpoints. This body of research has established air pollution as a major contributor to the global burden of disease, although substantial questions remain concerning the specific pollutant sources and chemical components of the urban air mixture most responsible for the observed effects. My research focuses on these unanswered questions, investigating the factors affecting a person's exposure to urban air pollution, the impact of measurement error in air pollution exposure studies, and the associations between specific pollutant components and sources and corresponding health responses.

6. My research involves working with particularly sensitive cohorts of human subjects such as children, seniors, and individuals with cardiorespiratory disease. My studies focus on small cohorts of human subjects (one or two dozen people on a research panel). Because I work with a small number of participants, I have access to specific and reliable measures of participant exposures and associated health responses. My panel study methods have been vigorously vetted using time-tested approaches that are widely accepted in the scientific community, including peer and human subjects review and replication. Panel studies, in particular, have been shown to be important designs for addressing questions involving air pollution exposures and corresponding health response, given their use of individual-level data (*i.e.*, non-ecologic data) for both exposures and a range of clinical, sub-clinical, and molecular level biological responses. These data are often less prone to specific errors, including exposure measurement errors, that may be present in larger non-panel-based designs.

7. My study designs typically require the collection of large amounts of very sensitive, personal, and identifiable data and information about my study participants. For example, I often collect, among a suite of personal biometric data, biological information of individual metabolic profiles in plasma, breath samples, and saliva, genetic information, lung function and cardiovascular measurements, and medication usage. I also routinely collect geographic and geospatial data about

where a subject resides and their mobility patterns throughout the day; I often will utilize continuous measurement of subject location throughout a study. I also collect sensitive personal information on socioeconomic status, race, income, and diet, among other variables and information sources.

8. I conduct research in this area with the goal of ensuring that my research may be used to protect sensitive and vulnerable communities, through informing regulatory standards. My previous work has been cited and used in preparing Integrated Science Assessments, which form the scientific basis for the EPA to review its health-based ambient air quality standards, and has been used in setting the standards.

9. I am aware that the EPA Administrator has just signed a rule, effective January 6, 2021, regarding how EPA may use studies examining "the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect" on human health. *See* 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021) (codified at 40 C.F.R. § 30.2) (the "Rule"). This action establishes new restrictions on the ability of EPA to consider such dose-response data for which underlying data cannot be made "publicly available in a manner sufficient for independent validation." *Id.* at 492 (codified at 40 C.F.R. § 30.5(c)). This requirement would limit EPA's ability to consider many vital public health studies, including the panel studies that I conduct, because they are based on confidential

personal information that cannot be legally or ethically disclosed—information which I would be restricted from releasing publicly by the established human subjects protections adopted by the Institutional Review Board (IRB) of my research institution, and most every other IRB with which I am familiar.

10. I would experience the effects of the Rule immediately. I am currently developing a grant application to submit to the National Institutes of Health ("NIH") for its February funding cycle for research that would involve human subjects. The application is due by February 5, 2021. The study for which I am seeking funding will use a panel study design to look at metabolic changes in asthmatics following exposure to traffic pollution. This research would seek to understand what biological mechanisms might be involved in how asthmatics respond to traffic pollution and would lead to an understanding of the susceptibility of vulnerable subpopulations to this type of exposure, as well as an understanding of what levels of exposure may be safe. I believe it would be considered "dose-response data" under the Rule. EPA currently has a network of near-road monitoring sites because the agency is concerned about health impacts from traffic pollution. My research, for which I am seeking NIH funding, would contribute to understanding safe levels of exposure to traffic pollution for particularly vulnerable groups, such as individuals with respiratory disease. In light of EPA's interest in this area, my hope and expectation

is that this work could constitute "pivotal science" that could help inform EPA's determination of appropriate health-based air quality standards.

11. The Rule will have immediate consequences for the viability of my grant application as planned. First, and most significantly, I understand that NIH considers the significance or impact research will have in making its funding decisions. If I were to keep my panel subjects' data confidential, under the Rule, my study would not be accorded its full weight as "pivotal science." That would have the potential to limit the likely impact of my research because it would be unusable or of limited use to EPA policymaking and, consequently, less likely to be funded by NIH. Addressing this problem by failing to guarantee subject confidentiality would subject my research protocol to being rejected by my (or any) IRB —and even if I could, I would incur considerable expense in ensuring that my data complied with the onerous requirements set forth in the Rule. The upshot is that the Rule puts me in an untenable position, unable to adopt an approach that would ensure grant funding of a viable panel study. If the Rule stands, I would be forced to choose between pursuing a protocol that would allow for EPA consideration and maximize the likelihood of NIH funding, but would be unlikely to obtain IRB approval—and a path of being able to get IRB approval, but making the study of limited value to EPA and unlikely to be funded by NIH.

12. Conversely, if the Rule were not in effect, I would not be faced with that dilemma. Based on previous experience with the Federal grant submission and approval process, I would expect to be more likely to receive funding and IRB approval, facilitating research to continue within my lab.

13. Failing to receive grant funding would have immediate consequences for my lab. My grant proposal will seek approximately $3-5 million in funding. This funding would likely support three to five staff and/or students and post-doctoral fellows at Emory University. If the grant were withheld because of the Rule's restrictions on EPA's consideration of the data or because a new design made the study less scientifically valuable, or if I decided I could not legally or ethically pursue the project consistent with the purpose of informing protective regulation, those jobs would be at risk.

14. Because of these concerns with the Rule, it will affect how I write the grant. To be able to expect grant funding and to ensure I could protect the jobs in my lab, I must represent that my research could be used as pivotal science, including in standard-setting processes for air pollution. But because the Rule will make that impossible with my planned panel design, I will have to substantially alter the protocol I have developed. This will take time and effort and ultimately could be fruitless. Abandoning the panel design would make my study less scientifically feasible because the analyses I propose to conduct are wholly based on

understanding individual-level exposure and response. Moreover, it is far from clear that even that redesigned study could be approved given the limited time I have available in which to rework my research approach.

15. More broadly, the Rule would not just affect my work on this study. I would have to consider shifting away from designing panel-based studies in the future, substantially changing the approach for which I conduct research and upon which I have built my career as an environmental health scientist. Because I want my research to continue to inform standard setting and policy (as it has previously), and because recruiting human subjects and receiving IRB approval for a study which would require release of sensitive biological information would be extremely difficult, I would dramatically rethink the type of designs that I use and the papers I write and pursue. Indeed, the irreconcilable choice the Rule would create—between having my research be able to inform EPA standard-setting and performing a study that could meet ethical and IRB requirements by keeping personal information confidential—would change the type of research I conduct and mean that there was certain research that I would decide not to do. As a consequence, the Rule would fundamentally undermine my ability to conduct research to contribute to setting health-protective air pollution standards.

16. On a personal and professional level, I have reached a stage in my career where I will soon be assessed for promotion to the rank of Full Professor.

Promotion will be based, in no small part, on my continuing and future ability to design and conduct relevant environmental health research, write and obtain federal funding from agencies such as NIH and EPA, and share the findings of this work with a diverse range of stakeholders, including, importantly, those in this country involved in developing policy and setting the standards related to the pollutant exposures I study, including in particular EPA.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 7, 2021

Jeremy Sarnat